Global Technical Steward Biologics and Cell Therapies (m/f/d) / Globalni ekspert proc. tehn. za bio. izdelke, celične in genske terapije (m/ž/d)

Job ID
REQ-10006857
Sep 03, 2024
Eslovenia

Resumen

#LI-Hybrid

As a Global Technical Steward Biologics, Cell and Gene therapies you will act as a key Subject Matter Expert in supporting the Novartis sites producing biologics cell and gene therapies as well as the Large Molecules Cell&Gene therapies platform leadership. Your contributions will include among others support to creation of development strategies, selection and introduction of new technologies, manufacturing process improvements, adaptations to new legislations, standardization efforts, benchmarking best practices, increasing site competencies and resolving complex process issues in collaboration with other experts on and above site.

You will report to the Global Head Manufacturing Science and Technology Large molecules CGT Platform.

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Kot Globalni ekspert procesnih tehnologij za biološke izdelke, celične in genske terapije boste delovali kot ključni strokovnjak za podporo Novartisovim lokacijam, ki proizvajajo biološke izdelke, celične in genske terapije, ter vodstvu Platforme za biološke izdelke, celične in genske terapije. Vaša vloga bo vključevala podporo pri oblikovanju razvojnih strategij, izbiri in uvedbi novih tehnologij, izboljšavah proizvodnih procesov, prilagoditvah novim zakonodajam, prizadevanj za standardizacijo, uvedbi dobrih praks, povečanju kompetenc lokacij in reševanju kompleksnih procesnih težav v sodelovanju z drugimi lokalnimi in globalnimi strokovnjaki.

Poročali boste Globalnemu vodji procesnih tehnologij za platformo.

About the Role

Key Responsibilities:

• Own the knowledge of specific pharmaceutical manufacturing process technologies at platform level – focus on drug substance manufacturing and cell therapy manufacturing.

• Act as the platform SME / SPOC for key topics at the interface with global Engineering, Technical Development and other organizations.

• Benchmarking new technologies and equipment relevant for platform. Participate in the definition and

selection of pharmaceutical equipment, through providing input to User Requirements. Provide technical expertise to Engineering for design activities in CAPEX projects around technologies.

• Assure that the necessary benchmark is done internally in Novartis, and externally in the scientific and academic environment, in order to stimulate and to extend the knowledge, increasing the know-how of the associates and expanding it to the rest of the organization.

• Author and implement GOPs for technology assigned.

• Participate in due diligence team evaluations, where applicable, for in-license projects.

• Strive to harmonize and optimize technical processes across the platform.

• Support sites in trouble shooting / root cause investigation by providing second level of specialist expertise as SME and by harmonizing and optimising related technical processes across the units.

• Set standards to perform technical feasibility trials related to process improvement and implementation of new manufacturing technologies.

• Maintain the work at a global level at inspection readiness level and provide the necessary support in any internal or external audit in addition to providing input to and review of regulatory documentation.

Essential Requirements:

• MSc. in Biochemistry, Biotechnology, Molecular Biology, Pharmacy, Pharmaceutical Technology, Chemistry or equivalent scientific degree. Desirable PhD. or equivalent experience.

• Fluent in English.

• Knowledge of MS Office.

• Minimum 10 years of work relevant to the specialist area of expertise (i.e. biologics DS process development & manufacturing, with mandatory experience from the ATMP area).

• Proven process understanding (GMP, ATMP Regulatory aspects, Product LCM).

• Complex project management experience (stakeholder management, cross-functional teams from multiple locations).

We offer a **permanent employment** with **6 months** of probation period.

You’ll receive:

Competitive salary, Annual bonus, Flexible working schedule, tailored to your needs, possibility to work from home, Pension scheme, Employee Recognition Scheme, Expanded program for the promotion of health in the field of physical, mental and social well-being (Energized for Life), employment at Top SI Employer, Unlimited learning and development opportunities.

Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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Vaše ključne odgovornosti:

• Lastnik znanja o določenih farmacevtskih proizvodnih tehnologijah na ravni platforme - fokus na proizvodnjo bioloških učinkovin, celičnih in genskih terapij.

• Biti strokovnjak za platformo in ključna kontaktna oseba za tehnične teme v projektih z globalnim inženiringom, tehničnim razvojem in drugimi organizacijami.

• Primerjava novih tehnologij in opreme (benchmarking), ki so pomembne za platformo. Sodelovanje pri opredeljevanju in izbiri farmacevtske opreme s podajanjem vloge zahtev uporabnika. Zagotavljanje tehnične strokovnosti inženiringu za oblikovanje v projektih kapitalskih naložb vezanih na tehnologije.

• Zagotavljanje, da je potrebno primerjanje opravljeno interno v Novartisu in eksterno v znanstvenem in akademskem okolju, da spodbudite in razširite znanje, povečate strokovno znanje sodelavcev in ga razširite na preostali del organizacije.

• Ustvarjanje in izvedba delovnih postopkov (GOP) za dodeljeno tehnologijo.

• Sodelovanje pri oceni ekip za skrbni pregled, če je primerno, za projekte s pridobivanjem licenčnih pravic.

• Prizadevanje za usklajevanje in optimizacijo tehničnih procesov na platformi.

• Podpiranje lokacij pri odpravljanju težav / preiskovanju vzrokov težav z zagotavljanjem strokovnega znanja in s prilagajanjem ter optimizacijo sorodnih tehničnih procesov na enotah.

• Določanje standardov za izvajanje tehničnih preizkusov izvedljivosti, povezanih z izboljšanjem procesa in uvedbo novih proizvodnih tehnologij.

• Izvedba aktivnosti v skladu z internimi in eksternimi standardi kakovosti, zagotavljanje podpore lokacijam v primeru notranjih in zunanjih inspekcij, svetovalna podpora in pregled relevantne regulatorne dokumentacije.

Vaš doprinos k delovnem mestu:

• Magisterij iz biokemije, biotehnologije, molekularne biologije, farmacije, farm. tehnologije, kemije ali druge ustrezne naravoslovne smeri. Zaželen doktorat ali enakovredne izkušnje.

• Najmanj 10 let delovnih izkušenj, ki so relevantne za področje strokovnega znanja (npr. razvoj in proizvodnja bioloških učinkovin, z obveznimi izkusnjami iz področja ATMP terapij).

• Dokazano razumevanje procesov (GMP, ATMP regulatorni vidiki, življenjski cikel izdelka).

• Izkušnje z upravljanjem kompleksnih projektov (upravljanje deležnikov, medfunkcionalnih ekip iz več lokacij).

• Aktivno znanje angleškega jezika.

• Poznavanje orodja Microsoft Office.

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedoločen čas** s poskusno dobo **6 mesecev.**

Kaj nudimo:

Konkurenčen plačni paket, letni bonus, fleksibilen način dela, z možnostjo prilagajanja urnika in delom od doma, zaposlitev v podjetju s certifikatom TOP Employer, pokojninsko shemo, shemo nagrajevanja in priznanja dosežkov, razširjeni program promocije zdravja na področju telesnega, duševnega in družbenega počutja (Polni življenja) ter dogodke, neomejene priložnosti za učenje in razvoj.

Predani smo raznolikosti in vključenosti

Novartis si prizadeva ustvariti izjemno, vključujoče delovno okolje in oblikovanje raznolikih timov, saj ti predstavljajo naše bolnike in skupnosti, ki jih oskrbujemo.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

División
Operations
Business Unit
Innovative Medicines
Ubicación
Eslovenia
Sitio
Ljubljana
Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.
Alternative Location 1
Barcelona Provincial, España
Alternative Location 2
Hyderabad (Office), India
Alternative Location 3

İstanbul Kurtköy, Turquía
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversity.inclusion_slo@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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